DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

SD BIOSENSOR, INC.
C/O PRISCILLA CHUNG
OFFICIAL CORRESPONDENT
2651 E CHAPMAN AVE STE 110
FULLERTON CA 92831

September 30, 2015

Re: K140827
Trade/Device Name: SD A1cCare System, SD A1cCare Spoit Type Test Kit, SD HbA1c Control Set
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: II
Product Code: LCP, JJE, JJX
Dated: August 21, 2015
Received: August 28, 2015

Dear Priscilla Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k140827

Device Name

SD A1cCare System, SD A1cCare Spoit Type Test Kit, SD HbA1c Control Set

Indications for Use *(Describe)*

The SD A1cCare System is a reflectometry immunoassay used for the quantitative measurement of glycated hemoglobin (%HbA1c) levels in fresh fingerstick capillary blood or venous whole blood samples. This system is intended for clinical laboratory and point-of-care use to monitor long term glycemic control of persons previously diagnosed with diabetes. This test is not for screening or diagnosis of diabetes.

The SD A1cCare Spoit Type Test Kit is part of the SD A1cCare System. It includes the test panel that receives the blood sample and is used with the SD A1cCare Analyzer for the quantitative measurement of glycated hemoglobin (HbA1c) levels in fresh fingerstick capillary or venous whole blood samples. The system is intended for clinical laboratory and point-of-care use to monitor long term glycemic control in persons previously diagnosed with diabetes. This test is not for screening or diagnosis of diabetes.

The SD HbA1c Control Set (Level 1, Level 2) and SD HbA1c Control Level M are intended for use as quality control materials for the SD A1cCare System.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

(k140827)

This summary of 510(k) information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter:	SD Biosensor, Inc. C-4th & 5th Floor, 16, Deogyeong-daero, 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, Republic of Korea443-702
Contact Person:	Yeon, Park QA/RA Assistant Manager Phone: 011-82-31-300-0416 FAX: 011-82-31-300-0497 py@sdbiosensor.com
Date Prepared:	September 29, 2015
Trade Names:	SD A1cCareSystem SD A1cCare Spoit Type Test Kit SD HbA1c Control Set
Classifications:	21 CFR 864.7470; Assay, Glycosylated Hemoglobin 21 CFR 862.1660; Quality control material (assayed and unassayed) 21 CFR 862.2160; Discrete photometric chemistry analyzer for clinical use
Product Codes:	LCP , JJE, JJX
Predicate Devices:	A1cNow+ (Professional Use) [k090413]; Bayer HealthCare Diabetes Care Afinion HbA1c Contols [k110056]; AXIS-SHIELD POC AS
Device Description:	The SD A1cCare System is a reflectometry immunoassay used for the quantitative measurement of glycated hemoglobin (HbA1c) levels in fresh capillary or venous whole blood samples. It is intended for professional use. The SD HbA1c Control Set is intended for use as quality control materials for the SD A1cCare System. The SD A1cCare System include the analyzer, analyzer check strip, DC power adapter, immunoassay test panels, lot-specific calibration code chips, and control set.
Intended Use:	The SD A1cCare System is a reflectometry immunoassay used for the quantitative measurement of glycated hemoglobin (%HbA1c) levels in fresh fingerstick capillary blood or venous whole blood samples. This system is intended for clinical laboratory and point-of-care use to monitor long term glycemic control of persons previously diagnosed with diabetes. This test is not for screening or diagnosis of diabetes. The SD A1cCare Spoit Type Test Kit is part of the SD A1cCare System. It includes the test panel that receives the blood sample and is used with the SD A1cCare Analyzer for the quantitative measurement of glycated hemoglobin (HbA1c) levels in fresh fingerstick capillary or venous whole blood samples. The system is intended for clinical laboratory and point-of-

	care use to monitor long term glycemic control in persons previously diagnosed with diabetes. This test is not for screening or diagnosis of diabetes. The SD HbA1c Control Set (Level 1, Level 2) and SD HbA1c Control Level M are intended for use as quality control materials for the SD A1cCare System.
Comparison of Technological Characteristics:	Like the predicate, the SD A1cCare System employs immunoassay technology to measure HbA1c from both capillary and venous samples. The SD A1cCare System provides quality control using a check strip, control set, and a lot-specific code chip for reagent test panels; whereas, the predicate has internal quality control checks for the analyzer, control solutions, and requires the user to match meter and reagent test cartridges to ensure proper calibration. Like the predicate, the SD A1cCare System requires simple preparation of the blood sample prior to application to the reagents. Like the predicate, the SD A1cCare System requires a 5 µL blood samples and display test results on a Liquid Crystal Display (LCD) within a few minutes. For control material, the predicate and the subject device have the same indication for use and the principle of operation. There are differences in number of levels, package, storage condition, shelf life time, use life time; however, the results of the performance tests provided in this submission support that the subject device is substantially equivalent to the predicate device in safety and effectiveness.
Functional and Safety Testing:	Bench testing addressed the following: NGSP certification, accuracy method comparison, linearity, precision, comparison of Spoit Type test kit performance, hematocrit range, interferences, hemoglobin variants, total hemoglobin, altitude, testing time, operating temperature range, optimal sample and mixture volume, anticoagulants, sample collection and preparation, stability of blood samples, vibration, temperature and humidity. EMC and electrical safety testing was done. Shelf-life testing was conducted on the reagent test panels and control sets. Software was subject to design control during development and comprehensive verification and validation testing. No animal testing was conducted. A user study clinical evaluation was conducted comparing home user results against a reference method which also evaluated ease-of-understanding of the instructions.
Conclusion:	The technological and functional characteristics of the SD A1cCare systems are substantially equivalent to that of the predicate product. All testing met acceptance criteria and support the contention that the SD A1cCare systems are substantially equivalent to the predicate product.